A. That is true. 11:58
Q. Which you have not read; correct? 11:58
A. Finished product testing for it? 11:58
Q. Right; correct? 11:58
A. I -- I can't say for sure I have not 11:58
seen some of the finished product testing results. 11:58
Q. Well -- 11:58
A. Because I have looked at some notebooks 11:58
and I don't recall whether they are specifically 11:58
related to finished product testing. 11:58
Q. Do you know as you sit here today 11:58
whether Actavis had out-of-spec finished product 11:58
test results with Digitek for any of the 152 11:58
recalled batches? 11:58
A. I have not seen any released testing 11:59
data -- 11:59
Q. Okay. 11:59
A. -- that supports that. 11:59
Q. Do you know how many of the Plaintiffs 11:59
in this litigation have had their tablets tested 11:59
by independent labs? 11:59
A. No idea. 11:59
Q. Do you know of any out-of-spec tested by 11:59
Plaintiffs? 11:59
A. I have no idea. 11:59

Q. Did Mr. -- 11:59
A. I haven't been involved with the 11:59
Plaintiff. 11:59
Q. Did Mr. Kilpatrick who was here with you 11:59
yesterday and today tell you that they tested some 11:59
of their clients' tablets at NMS labs in 11:59
Philadelphia and they were within spec? 11:59
A. No. 11:59
Q. Do you know how many tablets were tested 11:59
by FDA under the 484 program with Digitek? 11:59
A. The number, no. 11:59
Q. Or how many batches? 11:59
A. Not off the top of my head, no. 11:59
Q. So when you said nobody tested, that's 11:59
not correct. 11:59
A. Right. I disagree with that statement. 11:59
Nobody tested the known double-thick that came up 11:59
during investigations. 11:59
Q. The 20. 12:00
A. No, the 1,300 and others that were 12:00
identified throughout the course of 12:00
manufacturing. It's been found several times that 12:00
the double-thick has showed up. 12:00
Q. Yeah, but did they ever make it to 12:00
consumers? 12:00

A. Not that I know of, but they were never tested as part of the investigation. 12:00
Q. I understand. 12:00
A. Okay. 12:00
Q. But from time to time pharmaceutical companies are going to reject batches; is that right? 12:00
A. That's correct. 12:00
Q. Or parts of batches because they're out of spec in some way; right? 12:00
A. Parts of batches if they have a pre-approved protocol that allows for stuff like that. 12:00
Q. So Actavis could make a batch of Digitek, find that all or part of them were out of spec, and reject the batch; correct? 12:00
A. They could, yes. 12:00
Q. That's the way it's supposed to work; right? 12:00
A. Yes, it is. 12:00
Q. So let's talk about -- oh, by the way, while we're talking about testing, do most pharmaceutical manufacturers conduct in-process testing of size, weight, and hardness? 12:01
A. Tableting? 12:01

Q. Yes, in tableting. 12:01
A. In my experience, yes. 12:01
Q. So when they are checking, do they also perform visual inspections for color and black dots and anything else? 12:01
A. For in-process? 12:01
Q. Yeah. 12:01
A. I think that depends on the individual process being manufactured. 12:01
Q. Well, to some degree when you're looking at -- 12:01
A. Finished product, yes. 12:01
Q. Okay. When you're looking at in-process pharmaceutical, some of that involves power of observation; correct? 12:01
A. Yes. 12:01
Q. Now, if -- oh, by the way, a minute ago you said something about 1,300 extra thick. What batches, what documents, what are you talking about? Where do you get that number? 12:02
A. I may have misspoke on exactly that, but there is a citation in one of the EIRs with respect to sampling of 1,300. 12:02
Q. Do you know which EIR? 12:02
A. I'm looking at the 483s. 12:02

Q. I'll tell you what. Why don't we go on to a different topic? At the lunch break, I would like you to find the EIR or 483 that refers to that? 12:03

A. That refers to 1,300? 12:03

Q. Yes. 12:03

A. Sure. 12:03

Q. I'll write a note for you. 12:03

A. Okay. 12:04

Q. Okay. Let's assume that a customer called you in for a consulting arrangement and they told you that they wanted to find out whether -- they had made some double-thick tablets and they were interested in trying to figure out whether they had actually made it out of the plant to the distributor and all the way down to the consumer level; okay? 12:04

A. Okay. 12:04

Q. Now, in order to figure that out -- 12:04

A. Yes. 12:04

Q. -- would you want to look at finished product test data? 12:04

A. If I was going to solve that problem, I would. 12:04

Q. No, please listen. I'm not asking you 12:05

to solve a manufacturing problem of double-thick tablets. 12:05

A. Right. 12:05

Q. The inquiry is we just don't know -- 12:05

A. Right. 12:05

Q. -- and don't have the time to figure out whether -- 12:05

A. Right. 12:05

Q. -- these actually got to consumers. 12:05

A. Right, right. My point being is that as I said before, I'm not a recall expert. So I would source somebody in my consulting chain who is an expert in investigating products on the market that may be adulterated and has done recalls. I would not do -- undertake that myself. It's not my expertise. It's a different area altogether. 12:05

Q. Why is it a different area altogether? 12:05

A. It -- the whole concept of recall is very complex and involves all kinds of different outside agencies and coordinations. In fact, these companies actually hire people to do recalls themselves. Not themselves. They hire these places. Stericycle I believe is the one that was involved in helping out with this one. They go to 12:06

the outside. It's a unique set of skills. 12:06
Q. Okay. But the company that's consulting 12:06
here isn't necessarily conducting a recall. 12:06
They're just trying to figure out -- 12:06
A. Whether -- 12:06
Q. -- whether it's a problem and maybe 12:06
whether they should recall. Do you still farm 12:06
that out? Sorry for the colloquialism. Do you 12:06
still subcontract that to somebody else in your 12:06
consulting chain? 12:06
A. Again, if it's specifically looking at 12:06
the impact, is stuff out on the market? 12:06
Q. Yeah. 12:06
A. Yeah, I would seek additional expertise. 12:06
Q. Okay. And why is that not part of your 12:06
expertise? 12:06
A. The -- as you know from the readings, 12:06
the whole concept of GMPs and quality systems 12:06
encompass several major categories, and I don't 12:07
know of anybody personally that understands all of 12:07
those main quality system elements, and that has a 12:07
tendency quite honestly to fall to a regulatory, 12:07
which is even outside the main quality systems. 12:07
Q. So as part of your investigation in this 12:07
case and your opinions in this case, in order to 12:07

be consistent with your expertise, you would leave it to other experts to determine if out-of-specification Digitek made it to the market, and if so, how much; is that right? 12:07

A. If it made it to the market and how much. It wouldn't be binary -- you do it on or off if you will; okay? Hand it off. It would be something that I would be involved with from here are the data that suggests or show that adulterated product. 12:08

Q. Was made? 12:08

A. Was made. 12:08

Q. Right. 12:08

A. And could have potentially made it to the market. Then you do the handoff to the people that go out and try to assess that. 12:08

Q. Okay. So what you're really -- the core of your expertise and the core of your report is to analyze whether adulterated product was made -- the first half of the equation you just talked about; right? 12:09

A. And potentially made it to market. 12:09

Q. Right. 12:09

A. Uh-huh. 12:09

Q. Potentially, possibly. 12:09

A. Uh-huh. 12:09
Q. Right? Am I right? 12:09
A. Uh-huh. 12:09
Q. That's a yes? 12:09
A. Yes, I'm sorry. I keep forgetting it's not just you and I having the conversation. 12:09
Q. Look at page 7 of your report, please. 12:09
And I think we're using 92, Exhibit 92. 12:09
A. Got you. 12:09
Q. Got it? 12:09
A. Yeah. 12:09
Q. In the product recall section, on the right-hand side, the third one down says 2008 Class I Digoxin, double-thick or super-potent; okay? 12:09
A. Yes. 12:10
Q. Are you saying there normal size but too much active pharmaceutical ingredient? Is that what you mean by super-potent? 12:10
A. Yes. 12:10
Q. All right. So where in the FDA documents does it say anything about the April 2008 recall being about normal size but too much active pharmaceutical ingredient, super-potent Digitek? 12:11

A. In the FDA documentation? 12:11
Q. Correct, correct. 12:11
A. I don't believe there is anything in the FDA documentation after we talked about it. 12:11
Q. All right. 12:11
A. There is a statement in one of the original responses or drafts of the recall notice, if I remember, that they referred to overweight tablets which would imply super-potent. 12:11
Q. Overweight is a size issue, isn't it? Could have too many excipients in it, overweight? 12:11
A. It could be super-potent or sub-potent. 12:11
Q. Either one. 12:11
A. Because of blend uniformity issues that we talked about. 12:11
Q. It could be overweight and still have the right balance of pharmaceutical -- active pharmaceutical ingredient, couldn't it? 12:11
A. Balance? What do you mean by balance? 12:12
Q. Ratio. I mean in other words it could still be within the API specs and be overweight for some reason; right? 12:12
A. A dosage form is specific -- as you know is composed of actives and excipients and those ratios are very important. And not having that 12:12

proper ratio and dosage form can cause difficulties. 12:12

Q. Okay -- 12:12

A. In my experience. 12:12

MR. MORIARTY: Mike, Meghan, Terry, whoever, I'm going to start using my favorite documents, the 484s; okay? These are the ones I told you I was not bringing an extra set of because I had given them to everybody last week; okay? 12:12 12:13 12:13 12:13 12:13

MR. KERENSKY: Sure. 12:13

BY MR. MORIARTY: 12:13

Q. I'm showing you Exhibit 24. I'll represent to you that that is an FDA form 484 for Digitek. 12:13 12:13

A. Uh-huh. 12:13

Q. Have you ever seen it? 12:13

A. Miss Johnson gave me some documents the other day with respect to this type of thing. I could have looked at this. 12:13 12:13

Q. Is that the first time you had seen the 484s? 12:13 12:13

A. Yes. 12:13

Q. So did you have a chance to go through all of them? 12:14 12:14

A. I did scan through them. 12:14
Q. All right. 12:14
A. Yes. 12:14
Q. So, for example, Exhibit 24 was Digitek collected in February of 2007 by the FDA. 12:14
A. Uh-huh. 12:14
Q. Is that right? I mean that's who collected 484 samples; right? 12:14
A. I'll tell you I'm not an expert in the FDA's 484 and monitoring system. In fact I know very few people who really are experts in that. So this is my first exposure to the 484 program. 12:14
Q. Let me represent to you in February of 2007, FDA collected 200 count bottles of Digitek. 12:15
A. Uh-huh. 12:15
Q. It had to -- it came from batch 70078(a)(1). 12:15
A. Uh-huh. 12:15
Q. And FDA ran the tests that are described in Exhibit 24 and the Digitek passed all the tests to which it was subjected; okay? 12:15
A. Met the specification. 12:15
Q. Yes, met the specs. 12:15
First of all, do you have any reason to disagree with me on that? 12:15

A. No. 12:15
Q. Okay. Is it significant to you at all? 12:15
A. Significant? 12:15
Q. Yeah, is it significant in your analysis 12:15
of these cases that the FDA came in, tested the 12:15
product, sampled the product -- 12:16
A. Right. 12:16
Q. -- tested it. 12:16
A. Right. 12:16
Q. And it passed? 12:16
A. Right. I will tell you this: When I 12:16
first looked through here, I went oh, Jeez they 12:16
passed all the specs except for a few things in 12:16
here that are bit odd that I'm surprised nobody 12:16
picked up. For instance, some chromatography is 12:16
particularly ugly, which would lend problems. 12:16
Dissolution is a strange method that it's always 12:16
higher than the assay, which is problematic from a 12:16
scientific standpoint. 12:16
But in the end, when you look at the values, 12:16
it appears that they ran the assays and they met 12:16
the spec. Then when I stopped and thought about 12:16
it, it's like it doesn't really mean anything 12:16
because nobody is testing products that were 12:16
double-thick. You would expect to get decent 12:16

readings, results, for the most part. 12:16
Q. Why would you expect to get decent 12:16
results for the most part? 12:16
A. Well, the link being that, you know, 12:16
overweight or large tablets would imply that 12:16
there's -- there's something wrong with the dosage 12:16
and it would show up on assay, but nobody ever 12:17
analyzed any of those. 12:17
Q. Okay. So -- so did you conclude that if 12:17
the tablets weren't double-thick, they would most 12:17
likely meet their specifications if tested like 12:17
this? 12:17
MR. KERENSKY: Object as to form. 12:17
THE WITNESS: As talked about before, 12:17
it's a possibility that you could have a 12:17
tablet that isn't double-thick or super-potent 12:17
because of blend uniformity problems. All you 12:17
can say is that the product that they tested 12:17
here in the surveillance passed the spec. 12:17
That's all -- that's all you can conclude out 12:17
of it. 12:17
BY MR. MORIARTY: 12:17
Q. All right? 12:17
A. Nothing more. 12:17
Q. And they had the opportunity to test as 12:17

much as they wanted at that time; correct? 12:17
A. I don't know if that's a fair statement, 12:17
as much as they wanted. They did random 12:17
sampling. From what I understand, again I've just 12:18
recently been exposed to this program that it's a 12:18
random sampling, statistical sampling, and it is 12:18
in a lot of product. 12:18
Q. Well, they could have -- they could have 12:18
tested all 200 of the tablets that they secured; 12:18
correct? 12:18
A. They could have, but they didn't. 12:18
Q. Right. 12:18
A. Which is problematic if you're looking 12:18
for specific things, so... 12:18
Q. Do you assume that the FDA visually 12:18
inspected the 200 tablets that they did take 12:18
before they chose the ones to chemically test? 12:18
A. If their methods say they did, then they 12:18
did. I'm not sure what's in here as far as the 12:18
method goes. You realize that an analytical 12:18
method, if it's for assay, people if they're in a 12:18
hurry in particular don't necessarily take a look 12:18
at the dosage forms. 12:18
If the spec says, visual -- you know, I forget 12:18
the term right off the top of my head now, you 12:19

know, description. Then they sit down and they'll do a description and purposely look at it. 12:19

It's a problem when you're in a high-volume laboratory of people not actually looking at the dosage form and doing the test. I've had problems with it in my own people. 12:19

Q. Do you know anything about how high-volume the 484 program is? 12:19

A. No. 12:19

Q. And you don't know how carefully they looked at these tablets for size, weight, overall -- 12:19

A. I don't have -- 12:19

Q. -- aside from the ones they tested. 12:19

A. I don't have their methods, I don't have their notebooks, and I'm not in their facility. 12:19

Q. All right. 12:19

So Exhibit 25, had you ever seen this 484 before the other day? 12:19

A. I didn't see any 484-related documentations prior to the other day. 12:19

Q. All right. So this is another instance where the FDA went out, sampled Digitek, tested it in whatever manner they did, and found it to be within compliance with the specs. 12:19 12:20

Do you have any reason to disagree with that? 12:20
A. If that's what the document says, I -- 12:20
no. 12:20
Q. Okay. Do you think it's significant 12:20
that FDA once again found Digitek within specs 12:20
when they tested it? 12:20
A. No, I don't. When you look at the sheer 12:20
number of tablets that have been produced here, a 12:20
random sampling of certain lots at certain times 12:20
doesn't necessarily show you that there's bad 12:20
product out or not bad product out on the market. 12:20
Q. And it doesn't show you that there is; 12:20
correct? 12:20
A. I agree. 12:20
Q. All right. Had you seen Exhibit 26 12:20
before the other day? 12:20
A. Same thing. This is part of a 484. 12:20
Q. So once again it's FDA testing of 12:20
Digitek, finding it to be within compliance. Do 12:20
you think that's significant? 12:20
A. Finding the samples they tested to be 12:20
within compliance? 12:20
Q. Correct. 12:20
A. Uh-huh. 12:20
Q. Is it significant? 12:20

A. Again, the point being if this is not a -- nobody's ever tested -- we wouldn't even be having this conversation if somebody had taken the tablets that they found that were thick or thin and tested them and proved it wasn't a problem because then you'd know for sure that that -- that it's a problem. And nobody's done that. That's what really nagged at me through this whole thing. 12:21

Q. Does it nag at you at all that nobody in the course of your engagement in this has shown you a double-thick tablet that was actually in the hands of a consumer? 12:21

A. Yeah, I'm not sure -- 12:21

MR. MORIARTY: Read that back. 12:21

THE WITNESS: Yes, please. 12:21

(Whereupon, the testimony was read back by the court reporter, as recorded above) 12:22

THE WITNESS: Not as much, no. 12:22

BY MR. MORIARTY: 12:22

Q. So -- 12:22

A. It's -- 12:22

Q. Go ahead. Mike will get mad at me if I cut you off. 12:22

MR. KERENSKY: That's right. 12:22

THE WITNESS: I'm not an MD. From what 12:22

I've read in this case, this medication is frequently given to people who have heart problems and therefore are older. In my experience working with the generic industry, one of the things that they try to do is to make a dosage form very distinct and stand out as much as possible so elderly people won't confuse medication. 12:22

So I think it's very probable that an elderly person could have taken a double-thick tablet and not know about it. There's such trust in this country for what you buy from a prescription pharmaceutical. You put it in your mouth, you don't even think about it. 12:22 12:23 12:23

Heck, my wife is only 52 years old and she looks at her medicine case and she can't tell what she's taking if she doesn't have her glasses on. 12:23 12:23 12:23

So if it got out there -- and we know stuff's been out there -- and it was in somebody's medicine cabinet in their house, and they took it and not seen it, I think that's probable if it was there. 12:23 12:23 12:23 12:23

BY MR. MORIARTY: 12:23

Q. Okay. Probable. In other words more 12:23

likely than not? 12:23

A. I think that it's more likely than not 12:23
if they had a double-thick tablet that somebody 12:23
has taken them. 12:23

Q. If they had a double-thick tablet. 12:23

A. We know -- 12:23

Q. But you don't know whether it's probable 12:23
that anybody got one; right? 12:23

A. I don't agree with that statement. 12:23

Q. Okay, then show me the data. We have 12:23
thousands of lawsuits, dozens and dozens of 12:23
lawyers, TV advertising, nationwide recall, 12:23
everybody's focusing on Digitek. They could pour 12:23
them out on table in their lawyers' offices, but 12:24
no one has shown you one; okay? 12:24

Are you telling me that they ate them all by 12:24
coincidence? Is that what you're going to tell a 12:24
jury, yes or no? 12:24

A. That they ate them all? 12:24

Q. Consumed them all. 12:24

A. I don't think they necessarily consumed 12:24
them all. I think they might have been thrown out 12:24
or disposed on top of it all. 12:24

Q. Might have been; okay. 12:24

Are you going to tell a jury -- are you going 12:24

to tell a jury in this case that it is sheer coincidence that my client made enough double-thick Digitek to harm consumers but that that could not have been detected by Actavis, Mylan, UDL, pharmacists, or consumers. Is that what you're going to tell the jury? 12:24 12:24 12:24 12:24 12:25 12:25

A. I think that there's enough evidence here based on failures, systemic chronic failures of the quality system that product made it to market -- and we know that it did in at least a couple of circumstances with respect to pharmacists' reports. And that out of sheer volume of tablets produced that it got to the consumer and somebody took it and got hurt. 12:25 12:25 12:25 12:25 12:25 12:25 12:25 12:25 12:25

Q. All right. So you have one tablet in 2004 and one -- if you believe that report in 2008 -- out of somewhere close to a billion Digitek tablets; right? That's all that you know about; is that right? Yes or no. 12:25 12:25 12:25 12:25 12:25 12:25

A. Say that again, please. 12:26

Q. You have one report of a tablet in 2004 that was actually measured. You have a report maybe by somebody with the initials CSC after their name, looking at a blister pack, seeing a tablet in there that might have been 12:26 12:26 12:26 12:26 12:26

double-thick. That's two tablets between 2004 and 2008 out of close to a billion that were made and distributed. 12:26

Is that all the evidence that you have that double-thick Digitek made it to the hands of pharmacists or consumers? 12:26

A. With the data I've reviewed to this point, yes. 12:26

Q. Okay. So let me ask my question again. 12:26

A. Okay. 12:26

Q. Are you going to tell a jury that it is a -- that my client made enough out-of-specification Digitek to harm consumers but not enough to be detected by in-process, finished process testing at Actavis, any testing that Mylan, UDL did, and also escaped the detection of pharmacists and the FDA and the consumers themselves? 12:26 12:27 12:27 12:27 12:27

Is that what you're going to tell the jury, yes or no? 12:27 12:27

A. Yes. But I think there's enough information here to throw substantial doubt. I'll answer this question, too. I've been in this industry since 1992 and consulting for about 12 years now and at about day two in reviewing these 12:27 12:27 12:27 12:27 12:27

documents, especially with respect to the EIRs, this is the first time I went up to my medicine cabinet and I looked for anything that had an Actavis label on it and flushed it down the toilet because it is that gross in terms of what I was seeing. 12:27 12:27 12:28 12:28 12:28 12:28

MS. DONAHUE: Objection. Move to strike. Non-responsive. 12:28 12:28 12:28

MR. MORIARTY: Are you done? 12:28

THE VIDEOGRAPHER: Five minutes. 12:28

BY MR. MORIARTY: 12:28

Q. Are you done with that answer? 12:28

A. For now, yes. 12:28

MR. MORIARTY: Move to strike. 12:28

BY MR. MORIARTY: 12:28

Q. Here's Exhibit 27. Did you ever see it before the other day? 12:28 12:28

A. No, and I'm not sure if I saw this one for sure. I just -- I said before, the 484 stuff I have never saw before. 12:28 12:28 12:28

Q. Have you ever seen 28 before today -- before the other day, excuse me -- Exhibit 28? 12:28 12:28

A. No. 12:28

Q. Have you ever seen Exhibit 29 before the other day? 12:28 12:28

A. Before the other day, no, that I know of. 12:28

Q. Have you ever seen Exhibit 30 before the other day? 12:28

A. No. 12:29

Q. Have you ever seen Exhibit 31 before the other day? 12:29

A. As I said before, anything related to the 484 program I didn't have until yesterday. 12:29

Q. So then I assume the answer is the same to 32, 33, and 34, all of which are additional 484s done by the FDA, testing my client's product and finding it to be within its specifications. 12:29

A. For these particular lots and these particular samples. 12:29

Q. Have you ever seen an FDA report where they verified that a double-thick tablet made it to the marketplace in 2005, 6, 7, or 8? 12:29

A. In the documents I reviewed, no. 12:30

MR. MORIARTY: How many minutes? 12:30

THE VIDEOGRAPHER: We have three. 12:30

MR. MORIARTY: Let's just take our lunch break now. 12:30

THE VIDEOGRAPHER: The time is 12:31 p.m. We're going off the record 12:30

briefly. 12:30

(Lunch break) 01:09

THE VIDEOGRAPHER: The time is now 01:09

1:12 p.m. We are back on record. This is the 01:10

beginning of tape four. 01:10

BY MR. MORIARTY: 01:10

Q. One of the things that you were going to 01:10

do at the lunch break is find the reference to the 01:10

1,300 extra thick tablets. Did you find it? 01:10

A. Meghan found it and she left. So... 01:10

MR. KERENSKY: Let me call her. 01:10

MR. MORIARTY: She found it and didn't 01:10

give it to you? 01:10

MR. KERENSKY: She said she had it in 01:10

hand. 01:10

MR. MORIARTY: Okay. 01:10

MR. KERENSKY: Let's keep going and I 01:10

will see if I have -- 01:10

MR. FITZPATRICK: Here is what Meghan was 01:10

talking about. It's in your report. This is 01:10

what she's talking about. 01:10

THE WITNESS: Right. A-11, yeah. 01:10

MR. MORIARTY: Can somebody clue me in? 01:10

THE WITNESS: A-11. 01:10

MR. FITZPATRICK: No. 01:10

BY MR. MORIARTY: 01:11

Q. A-11 is the reference which in your index says FDA form 483, observation from inspections spanning October 29 to November 2001; correct? 01:11

A. That's what it says in the report, yes. 01:11

Q. And it has to do with -- 01:11

A. Here we go. 01:11

Q. And it has to do with thin tablets observed by packaging personnel and they visually inspected and rejected 1,600 tablets; is that right? 01:11

A. During packaging, 1,600 tablets, yes. 01:11

Q. Thin? 01:11

A. Thin, short weight. 01:11

Q. Well, first of all, I know we covered this earlier, but these aren't tablets that were even close to the recall period; correct? 01:12

A. The recall was in? 01:12

Q. The recall was in April of '08. 01:12

A. Okay. 01:12

Q. For tablets going back about two years. 01:12

A. Yes. 01:12

Q. So this isn't even close to the recall period; right? 01:12

A. No. 01:12
Q. And this isn't -- this 483 that you're 01:12
referring to -- your A-11 -- reference, isn't 01:12
about thin tablets that made it out of the plant 01:12
and to consumers; correct? 01:12
A. This specifically has to do with their 01:12
process and procedure for detecting these types of 01:12
tablets. 01:12
Q. Which -- 01:12
A. The observation. 01:12
Q. Which they detected and rejected; 01:12
correct? 01:12
A. Those specific ones, but as the 01:12
observation says here, there's no assurance that 01:12
this was taken care of properly and it could have 01:12
expanded. 01:13
Q. Did you ever see any report from any 01:13
document -- FDA or a company -- to indicate that 01:13
there were thin tablets in the hands of 01:13
pharmacists or consumers in 2001 or 2002? 01:13
A. Perhaps. 01:13
MR. MORIARTY: Go off the video record, 01:13
please. 01:13
THE VIDEOGRAPHER: The time is now 01:13
1:16 p.m. and we're going off the record 01:13

briefly. 01:13

(Short break) 01:14

(The following questions are not on the video record but were recorded by the court reporter) 01:14

THE WITNESS: Comes back to a recall in 1990 Class II, due to thickness. 01:14

BY MR. M0ORIARTY: 01:14

Q. Dr. Bliesner, I'm asking about your A-11 reference, the rejection of 1,600 thin tablets in 2001. 01:14

A. Yes 01:14

Q. And my question was, was there any evidence that thin tablets made it to pharmacists or consumers in 2001 or 2002? 01:14

A. In 2002? I'm sorry. I didn't hear the dates on it. I thought you said ever. And ever was is that, yes, there was a recall for thin tablets back in 1990 for the same company that's making this stuff now. 01:14

Q. My question was have you got any evidence that thin tablets were in the hands of consumers in 2001 or 2002 as a follow-up to this 483 that you referred to as A-11? 01:15

A. I haven't seen a documentation for 2002, just this one. 01:15

Q. Do you have some documentation that thin tablets were in the hands of pharmacists and consumers when they did that recall in 1990 that you were just talking about? 01:15

A. I don't have any documents to support that. Just what was given to me. 01:15

Q. So you don't have some reference to 1,300 super- or double-thick tablets anywhere? 01:15

A. I misspoke. It was the 1,600. 01:15

Q. All right. No, but I'm talking about 13 or 1,600 extra-thick tablets in '05, '06, '07 or '08. 01:15

A. No. 01:16

Q. Okay. This is Exhibit 35. Have you seen this? Did you see this ever -- and if so, when? 01:16

A. This may be part of the document set that was given to me yesterday along with the 484 stuff. 01:16

Q. Well, did you look at it? 01:16

A. If it's part of that set -- which I can check -- the answer would be yes. I'll check. 01:16

Q. Watch out. The screen is on the back of your chair. Are you looking for the document itself or a list? 01:17

A. No, the document itself. 01:17
Q. Bring them all over. 01:17
A. All right. 01:17
Q. Because I've got plenty to ask you about. 01:17
A. Okay. 01:17
THE VIDEOGRAPHER: Just so we're clear, we're still off the video record. 01:17
MR. MORIARTY: You mean I asked him that whole sequence of questions about the 1,300 tablets and I wasn't on the video? 01:17
THE VIDEOGRAPHER: Yes. 01:18
MR. MORIARTY: You got it? 01:18
THE COURT REPORTER: Yes, I did. 01:18
(Back on the video record) 01:18
BY MR. MORIARTY: 01:18
Q. Okay. And this is -- UDL or Mylan subcontracted with Celsis Analytical Services to test three samples from three batches of Digitek; correct? 01:18
A. Yes, there's Digitek 250, Digitek 250, Digitek 125. 01:18
Q. And did you read -- 01:18
A. Different ones. 01:18
Q. Did you read in here that the Digitek 01:18

samples that they tested passed all the tests to which they subjected it? Would you like the Bates page numbers? The first one, 11687. Do you see that? 01:19

A. Assay and dissolution; right? Are you speaking to me? 01:19

Q. Yes. 01:19

A. I'm looking at the document. 01:19

Q. I'm giving you the page number to look at. 01:19

A. I'm sorry. I didn't understand that. 01:19

Q. 11687. 01:19

A. 11687; okay. 01:19

Q. And it -- this particular batch, they ran it assay and a dissolution; correct? 01:19

A. Right. 01:19

Q. And it conformed to both. 01:19

A. Right. I was looking at the results over here with respect to the certificate of analysis, which has a summary of it all on the previous page. 01:19

Q. Next page, 11719. Are you there? 01:20

A. No, I'm not. And this is the one with the ugly chromatography. Makes you kind of question the results a little bit. 01:20

Q. So you have -- 01:20
MS. DONAHUE: Move to strike. 01:20
BY MR. MORIARTY: 01:20
Q. You have a problem with the 01:20
chromatography from both Celsis and FDA? 01:20
A. I don't recall. 01:20
Q. Because we were talking about FDA 01:20
before. 01:20
A. Before, yes. This -- just looking at 01:20
this, the chromatography is a little bit suspect. 01:20
Q. So you have suspect chromatography from 01:20
FDA and Celsis? 01:20
A. I didn't say that about the FDA. 01:20
Q. Yes, you did. That's what we were 01:20
talking about was a 484 from FDA. 01:20
A. Right. And we didn't specifically talk 01:20
about chromatography. 01:20
Q. Okay. The record will say what the 01:20
record says. 01:20
A. Okay. 01:20
Q. C11719. This batch tested for again 01:20
assay and dissolution. It conformed to both. 01:21
A. I'm actually looking at the certificates 01:21
of analysis, which are a better summary, which is 01:21
in the pages before. 01:21

Q. But the certificate of analysis comes from Actavis, does it not? 01:21

A. No, I'm pretty sure that this is a summary of the certificate of analysis from -- perhaps not. Let's see. 01:21

Q. What page are you looking at? 01:21

A. The previous page. 11718. 01:21

Q. Doesn't it says Actavis Totowa, LLC, right at the top? 01:21

A. Yeah. That doesn't necessarily mean that that's Actavis's data. Let's see. Is it their C of A.? You can't just assume it. Sometimes labs put the client's name at the top of the documents, so... 01:21

Q. Look at 11719, which is Celsis' report of analysis. 01:21

A. Okay. 01:22

Q. Did the Digitek conform to the two tests to which they subjected it? 01:22

A. Let's see. Conforms, yes, for assay and dissolution. 01:22

Q. Let's go to page 11748, the report of analysis from the third batch that they tested. Did it pass assay and dissolution? 01:22

A. Yes, for the samples they tested. 01:22

Q. Was Exhibit 69 among the materials that the Plaintiffs' lawyers supplied you the other day. Does it look familiar? 01:22 01:23 01:23

A. I -- to tell you truth, I can't -- I'm looking at so many different documents. To make a statement that I've looked at this, it's just not possible. And many of these documents I looked at six months ago, didn't even come close to reviewing it until two days ago. So you'll have to bear with me. I apologize. Yes. 01:23 01:23 01:23 01:23 01:23 01:23 01:23 01:23

Q. So you had it to review? 01:24

A. I did. 01:24

Q. And they received this Digitek in April of 2008 right before the recall; correct? First page, right at the top. Date received. 01:24 01:24 01:24

Do you see that? 01:24

A. I do. I'm looking at the receiving inspection form instead, which I trust more than the electronic printout. Okay. They inspected it in April 2008, yes. 01:24 01:24 01:24 01:24

Q. And if you go back to page 7655? 01:24

A. Uh-huh. 01:24

Q. They measured 20 Digitek tablets, didn't they? 01:24 01:25

A. Uh-huh. 01:25

Q. And they were all within the specs, 01:25
weren't they? 01:25
A. For the 20 they measured, yes. 01:25
Q. Does it appear to you that they 01:25
subjected it to any additional analysis? 01:25
A. Based on what document? 01:25
Q. Well, the one in front of you, Exhibit 01:25
69. 01:25
A. Okay. 01:25
Q. It doesn't appear to you that they did 01:26
assay or dissolution; correct? 01:26
A. I'm looking. 01:26
Q. Just from skimming through, do you see 01:27
any assay? 01:27
A. Yeah, I do. That's why I'm taking my 01:27
time. Because it look like they're making an 01:27
assay. 01:27
Q. Are you looking at the certificate of 01:27
analysis or -- 01:27
A. No, I'm not. I'm looking at this letter 01:27
here and I'm trying to determine. It's very 01:27
difficult to look at somebody else's testing and 01:27
control documents because they're not all the 01:27
same. 01:27
Q. And what page are you looking at? 01:27

A. I'm looking at 7656, the Mylan quality assurance assay result. We acknowledge the assay result is outside UDL's parameter, which is interesting. So UDL tested it and it was out -- for assay and it was outside their parameters. 01:27

Q. Was it outside the ANDA FDA-approved United States pharmacopeia specifications? 01:27

A. I don't know. 01:27

Q. Do you know what the USP specs are? 01:27

A. I don't have the USP in front of me, yes. 01:27

Q. If you assume that it was 90 to 105 percent, then this would be within the specs; correct? 01:27

A. I'm not going to assume anything. 01:28

MR. KERENSKY: He's allowed to ask you that type of question. 01:28

THE WITNESS: Yeah, but... 01:28

MR. KERENSKY: If that's the true spec. Is that what they found? 01:28

THE WITNESS: What did you say was the true spec to be? 01:28

BY MR. MORIARTY: 01:28

Q. 90 to 105 percent? 01:28

A. 90 to 105? If that assay limit is 97.4, 01:28

then it does fall within that -- if that's the case. But it doesn't fit UDL's one. 01:28

Q. Do you know whether people have testified in this case that UDL's specs are tighter than the ANDA FDA-approved USP specs? Simple question. Do you know anybody who testified to that? 01:28

A. I know it's a simple question. I'm just trying to remember the documents that I reviewed, as to whether in fact there is a statement to the effect that there is a tighter spec. As far as testifying goes, not that I know of. 01:28

MR. KERENSKY: Very good. That's all he's asking you. 01:29

THE WITNESS: Okay, okay. 01:29

MR. MORIARTY: Exhibit 70. This is a UDL analysis documents for another batch of Digitek they received in February of 2008. 01:29

THE WITNESS: Okay. Assuming the date format 3/5/08 is February, yes. Or March rather. 01:29

BY MR. MORIARTY: 01:29

Q. So at page 7671, did they measure 20 more Digitek tablets? 01:29

A. It appears they did, yes. 01:29

Q. And were they all within the specs as far as you know? 01:29

A. It's a good point. I don't know if I have the written specs here to do that, but assuming that the range is appropriate as stated on here, then, yes. I don't have the spec sheet. I don't think it's here, is it? C of A. Let's see. No. It's a good point. What spec are they using? 01:30

Q. Well, the ANDA -- the FDA would have approved a thickness range in the ANDA; correct? 01:30

A. Correct. And but the key being here is, is that we don't know what UDL specs they're referring to, what the spec is. 01:30

Q. My question is whether it's passing the FDA-approved USP specs. 01:30

A. I don't know. 01:31

Q. Okay. 01:31

A. It's not here. 01:31

Q. So now I've asked you about a number of FDA 484s and I've started to ask you about these UDL and Celsis lab documents. Do you know how many of the batches that have been tested in the documents that I've asked you about so far are among the recalled batches? 01:31

A. No, I don't know that number. 01:31
Q. This is Exhibit 71. Was it among the 01:31
materials that you reviewed in the last few days? 01:31
A. Yes. 01:31
Q. At page -- this is a Digitek batch 01:31
received at UDL in January in January of 2008; 01:31
correct? 01:32
A. Yes. 01:32
Q. And at page 7688 did they measure 20 01:32
more? 01:32
A. Yes. 01:32
Q. Is there any indication in this document 01:32
at all that any of them were outside the 01:32
FDA-approved specifications? 01:32
A. Again, I'm not trying to be difficult. 01:32
I don't know what the FDA specifications are. I 01:32
have to assume that that's what they're measuring 01:32
them against. There's no spec sheet, there's no 01:32
method, there's no nothing. 01:32
Q. All right. 01:32
A. Chances are if what you're saying is 01:32
correct that that UDL has -- you implied that UDL 01:32
has a tougher standard, this may be tougher or may 01:33
be wider. I don't know. 01:33
Q. Okay. 01:33

A. I see the assay was low again, too. 01:33
Q. Is that assay outside the US FDA -- the 01:33
United States Food and Drug Administration's 01:33
approved specs for this product? 01:33
A. If we go with your statement, what was 01:33
it 98 to? 01:33
Q. 90 to 105 percent. 01:33
A. 90 to 105, yes, then it would fall in 01:33
that spec. 01:33
Q. This is Exhibit 72. Is this a Digitek 01:33
batch received by UDL in June of 2007? You can 01:33
just look at the one I gave you. You don't need 01:34
to pull out your own. 01:34
A. All right. 01:34
Q. Is that what this is? 01:34
A. June. 01:34
Q. 2007? 01:34
A. Yes. 01:34
Q. Okay. And at page 5815 I believe it is, 01:34
did they measure 20 more? 01:34
A. They did. 01:34
Q. Any indication that any of them are 01:34
outside the FDA-approved specs? 01:34
A. Unlike the assay -- perhaps, you know. 01:34
Do you know what the thickness that the filed spec 01:34

is? Because they do point out that it failed UDL's thickness, and we don't know whether it's tighter or wider than -- 01:35

Q. We do know because there's been testimony. Their specs are tighter than the FDA's approved specs. 01:35

A. Okay. Because those -- 01:35

Q. Those all passed. 01:35

A. They did fail -- four tabs failed thickness here, but the spec that UDL has, they're measuring this right here, that -- that is -- the question here is that is the filed spec, do we know that? 01:35

Q. What page? 01:35

A. The one you had me look at, 5815 is it? 01:35

Q. There is no spec on that page. 01:35

A. No. 01:35

Q. So my question is just is there any indication in the document that any of the tablets were outside the FDA's approved specs for the product? 01:35

A. We can't say that one way or the other because we don't have the USP spec for thickness or the file spec. 01:36

Q. You don't know the answer to the 01:36

question. 01:36

A. I'd know the answer to the question if I had the spec from the ANDA. It's not here. 01:36

Q. I'm showing you what has been marked as Exhibit 73; okay. 01:36

A. Would you like me to check these and see if I had this before? 01:36

Q. No, sir. Look at the second page and -- 01:36

A. 478969? 01:37

Q. Yes. Okay. Do you see the specs for Actavis and UDL at the top? 01:37

A. I'm looking. 01:37

Q. Do you see that? 01:37

A. I see that. 01:37

Q. Aren't the UDL specs tighter than the Actavis specs? 01:37

A. The reason I'm hesitating is I'm seeing how it's written, and I'm trying to make sure that I got it in the right order. So please bear with me. Actavis has -- on the 250 microgram tablet, Actavis has narrower limit than UDL has. On the upper end, they do as well. So they're different and -- tighter is not -- 01:37 01:38 01:38 01:38 01:38

Q. Okay. Let's go back to basic math here. 01:38

A. Yeah. 01:38
Q. If the FDA-approved range for .250 01:38
microgram Digitek is 2.7 millimeters to 3.7. 01:39
A. Right. 01:39
Q. 3.15 to 3.29 -- the UDL spec -- is 01:39
tighter? 01:39
A. Broader; right. 01:39
Q. No, actually it's tighter. 01:39
A. The UDL? 01:39
Q. It's narrower. Isn't 3.15 larger than 01:39
2.7? 01:39
A. Yeah. 01:39
Q. And isn't 3.29 less than 3.7? 01:39
A. The way this is written -- 01:39
Q. Yes or no. Is -- 01:39
A. No, no, no, no. 01:39
Q. Is 3.29 less than 3.7? 01:39
A. On that one, yes. 01:39
Q. Okay. 01:39
A. But on the other end, it's not. 01:39
Q. 3.15 is -- 01:39
A. Is broader. You've got a broader range 01:39
between those two specs than you do for Actavis. 01:39
Q. Okay. Tell you what. Let's look at the 01:39
sentence: 01:39

"It should be noted that UDL's tolerances for creation of blister cavity size are tighter than the manufacturer's tolerances for thickness and UDL's maximum tolerance is used during the creation of blister tubing." 01:39 01:40 01:40 01:40 01:40

Are you writing on that too?" 01:40

A. No, I'm not. 01:40

Q. Did I read that correctly? 01:40

A. Yes. 01:40

Q. Are you telling me that UDL is wrong? 01:40

A. Okay. The thickness variance between 3.7 and 2.7 is 1.0; okay? If you go 3.29 to 3.15. All right. Okay. .14. You're right. I just want to make sure. 01:40 01:40 01:40 01:40

Q. Okay. So, the Actavis specs are -- FDA-approved that Actavis specs are wider than UDL's for both doses. 01:40 01:40 01:40

A. Yes. 01:40

Q. Okay. 01:40

A. Just the range is different. 01:41

Q. Okay. I'm handing you what has been marked as Exhibit 83. This is a correspondence between UDL and Celsis, is it not, about Digitek tablets? 01:41 01:41 01:41 01:41

A. This is a report -- what was the 01:42

question again? 01:42
Q. Is this a communication between UDL and 01:42
Celsis about three batches of Digitek that they 01:42
were testing for stability. It's more than three 01:42
batches. Is this what this is about is stability 01:42
testing and Digitek? 01:42
A. It appears to be about stability 01:42
testing, and I think there is more -- you're 01:42
correct on that. 01:42
Q. When you run stability testing, do you 01:42
also run assay? 01:42
A. Yes. 01:42
Q. Did the Digitek that they tested in 01:42
Exhibit 83 pass all the specs? Why don't you go 01:43
off the video record while we -- 01:44
THE VIDEOGRAPHER: The time is now 01:44
1:47 p.m. We are going off the video record 01:44
briefly. 01:44
(Short break.) 01:47
THE VIDEOGRAPHER: The time is now 01:48
1:51 p.m. We are back on record. 01:49
BY MR. MORIARTY: 01:49
Q. Did it pass all the tests to which 01:49
Celsis and UDL subjected it for stability and 01:49
assay? 01:49

A. Yes, but it goes to Stage II to dissolution on a couple, and there's no upper-end spec on dissolution. And there's some numbers in here that if I was running the lab, that I would question. 01:49

Q. Okay. So we've now gone through -- and you didn't look at the batch records to see Actavis's finished product test results. And we've now gone through the 484s and testing done by other companies outside Actavis; okay? 01:49

Do you have any test data to indicate that Digitek in 2005, 6, 7 or 8 was outside its specifications test data? 01:49

A. Test data? I have not seen any testing data, but nobody had ever tested the double-thick tablet. 01:50

Q. So can I make the assumption, Dr. Bliesner, that you are reaching your conclusions in this case based on FDA 483s, warning letters, FDA documents like that, as opposed to actual test data of product? 01:50

A. I'm basing my conclusions not only on FDA-related documentation but also e-mails, process validation, blend uniformity results and reports and investigations that the company did as 01:50

well, which are problematic with respect to the manufacturing of Digitek in my opinion. 01:50

Q. Show me a document anywhere that -- where the FDA questions the process validation of Digitek. 01:51

A. Within a specific time frame or -- 01:51

Q. 2005, 6, 7 or 8. I mean do you have any evidence that people in this litigation took tablets from the 90s or the early 2000s? 01:51

A. I have no idea. I doubt it. 01:51

Q. Do you know what the expiration is on this product? 01:51

A. I do not. 01:51

Q. So? 01:51

A. It's reasonable to be assumed that no. 01:51

Q. What I want to know is if you have some data from FDA from 2006, 7, or 8 to indicate that Actavis's process validation on the manufacture and testing of Digitek was a problem. 01:51

Go off the record again. 01:52

THE VIDEOGRAPHER: The time is 1:55 p.m. 01:52

We're going off the record briefly. 01:52

(Short break) 01:55

THE VIDEOGRAPHER: The time is now 01:55

1:58 p.m. We are back on the record. 01:56

THE WITNESS: If you look at the warning letter that was issued in February 2007, one of the findings by the FDA is no procedures for conducting bulk hold time studies. In my opinion and experience that, again, back to this warning letter, it says procedures for conducting bulk holding time studies. That falls into the purview of process validation. 01:56

So the answer would be yes, based on that warning letter. 01:56

MR. ANDERTON: What page of the report are you referring to? 01:56

THE WITNESS: I'm going through my document. 01:56

MR. ANDERTON: I understand. What page? 01:56

THE WITNESS: I would need to pull out the -- 01:56

MR. KERENSKY: What page of the report? 01:56

MR. ANDERTON: What page of the report are you looking at? 01:56

THE WITNESS: I'm sorry. 41. 41, 42. Goes over to 42. 01:56

BY MR. MORIARTY: 01:57

Q. From a February 2007 warning letter; right? 01:57

A. Correct. 01:57
Q. Actually doesn't say anything about 01:57
process validation, does it? 01:57
A. Bulk holding time would be part of the 01:57
process validation in my experience. 01:57
Q. That's nice. I'm asking whether the 01:57
warning letter says something about the process 01:57
validation or whether it just refers to bulk 01:57
holding times. 01:57
A. I'll have to go back to the EIR to look 01:57
specifically at that section. 01:57
Q. Well, what is -- first of all, did it 01:57
relate to Digitek? 01:57
A. Unless I go back and look at the report, 01:57
I can't answer that question. 01:57
Q. So you can't identify for me right now 01:57
-- 01:57
A. In this document. 01:57
Q. -- whether there's anything specific to 01:57
Digitek? 01:57
A. No, I'm going back to the FDA document. 01:57
Q. Do you know whether that observation is 01:58
remediated and whether the FDA was satisfied with 01:58
the company's actions in that regard for whatever 01:58
product that was? 01:58

A. Specifically, no. However, considering they went to consent decree, I doubt if they did. 01:58

Q. Okay. Let me just make clear while we -- see if we can find that. As you sit here right now, you don't know if that was a finding specific to Digitek; correct? 01:58

A. Correct. 01:59

Q. And you don't know as you sit here now whether it was remediated to the satisfaction of FDA; correct? 01:59

A. That's a fair statement. 01:59

Q. Right. 01:59

A. The fact that it relates to Digitek or not is an interesting question in itself because if you are not doing those kind of things, it is a failure of your quality system in general and manufacturing controls. 01:59

Q. But as you, as a consultant, would you want to know what specific drug products that impacts? 01:59

A. Sure. But in a bigger picture you'd want to make sure that it's not impacting -- you don't have the system in place that's going to impact everything. 02:00

Q. Okay. I'm handing you Exhibit 63. Have 02:00

you ever seen this section of the regulatory procedure manual? First of all, did you ever read the regulatory proceduring manual from the FDA? 02:00

A. If you can find it. Because the links change frequently and it's often difficult to find these kinds of things. 02:00

Q. But you do consult with it from time to time? 02:00

A. Rarely. 02:01

Q. Okay. 02:01

A. Maybe once or twice. 02:01

Q. Let's go to page -- the second page. 02:01

A. Uh-huh. 02:01

Q. Page 4-2? 02:01

A. Uh-huh. 02:01

Q. Fourth full paragraph. 02:01

A. Okay. 02:01

Q. The first sentence says: 02:01

"A warning letter is informal and advisory." 02:01

Do you agree with the FDA on that statement about their own documents? 02:01

A. Informal and advisory. I've obviously never read this section before. It's what it says. 02:01

Q. Okay. Well, it's the FDA commenting on 02:01

the force and effect of its own documents. Do you have some reason to disagree with the FDA in that regard? 02:01

A. In my experience, the answer to that, yes. Because in my experience a warning letter is taken with great seriousness and remediation actions spin-off of it. I'm in a major consulting project right now, responding to a warning letter -- as numerous companies are in the industry. You don't just take it as informal. You address it. It's standard industry practice. 02:01 02:01 02:01 02:02 02:02 02:02

Q. Well, you're looking at it from the perspective of the company when you just answered that question are you not? 02:02 02:02 02:02

A. I would I'm looking at it from the perspective of the agency, too. The agency expects you to respond to a warning letter pretty seriously as well. That's why it goes to the CEO. 02:02 02:02 02:02

Q. The FDA has a regulatory procedures manual, and in it, it says that a warning letter is informal and advisory. And you disagree with the FDA on an announcement that they make in their own publication; am I correct? 02:02 02:02 02:02 02:02

A. I'm not disputing what it says here, but the reality on the ground is that warning letters 02:02 02:02

by the agency and -- all companies is taken with great seriousness, and they surely are not addressed in an informal and advisory fashion. 02:02 02:03 02:03

Q. Okay. 02:03

A. That's my professional opinion. 02:03

Q. Third sentence of that paragraph: 02:03

"FDA does not consider warning letters to be final agency action on which it can be sued." 02:03 02:03

Do you agree with that or disagree with that? 02:03

A. "FDA does not consider warning letters to be final agency action on which it can be sued." 02:03 02:03 02:03

I was under the impression that you can't sue the FDA. Maybe I'm wrong. 02:03 02:03

Q. Do you disagree with the statement or not? 02:03 02:03

A. It's not final agency action by any stretch of the imagination. 02:03 02:03

Q. Okay. Thank you. 02:03

Next page, 4-3, under the first paragraph. At the margin it says "in certain situations." Do you see that? Item number 4 under that uses the word super-potency. Is that a -- is that term in the industry that you understand? 02:03 02:04 02:04 02:04 02:04

A. Sub-potent or super potent? 02:04

Q. It says super-potency; right there? 02:04
A. Yes. 02:04
Q. That's a term you understand. 02:04
A. Sub-potent, super-potent, yes. 02:04
Q. I'm showing you Exhibit 64. This is a 02:04
different chapter in the regulatory procedures 02:04
manual. I would like you to go to page 10-6. 02:04
A. Okay. 02:05
Q. Section 10-2-3. It says: 02:05
"When it is consistent with the public 02:05
protection responsibilities of the agency and if a 02:05
violative situation does not present a danger to 02:05
health or does not constitute intentional, gross, 02:05
or flagrant violations, it is FDA's policy to 02:05
afford individuals and firms an opportunity to 02:05
voluntarily take appropriate and prompt corrective 02:05
action prior to the initiation of an enforcement 02:05
action." 02:05
Is that consistent with your experience? 02:05
A. Yes. In that voluntary can mean a 02:06
consent decree, as you pointed out earlier. 02:06
Q. Okay. Let's go to the next page, 10-7. 02:06
Under 10-2-4, procedures: 02:06
"Warning letters are the principal means by 02:06
which the agency provides prior notice of 02:06

violations and of achieving voluntary compliance." 02:06

Did I read that correctly? 02:06

A. That's what it says. 02:06

Q. Is that consistent with your experience? 02:06

A. No. It's always been my understanding that the 483 was the first documentation of lack of compliance. 02:06

Q. Okay. Well, later -- but a warning letter is a means of getting voluntary compliance, whether it comes first or second. That's the point of it; right? 02:06

A. It is a step up in the ladder with respect to seriousness of lack of compliance. That's what it is. 02:07

Q. At the end of paragraph I was reading from it says: 02:07

"Other less formal ways include the following." And item two is the 483; correct? Is that what it says? 02:07

A. I -- 02:07

Q. Is that what's there? 02:07

A. This is -- this is what it says. But I can tell you 483s are not informal by any stretch of the imagination. 02:07

Q. Well, FDA says they are; correct? 02:07
A. In their documents manual that's what 02:07
they do. 02:07
Q. Okay. 02:07
A. But in reality in the world, 483s are 02:07
not informal. 02:07
Q. All right. So if a warning letter is 02:07
not a final agency action, and a 483 is considered 02:07
by FDA less formal than a warning letter, you 02:07
would agree that FDA doesn't consider 483s to be 02:08
final agency action; is that true? 02:08
A. Say that again, please. 02:08
Q. In your opinion is a 483 a final agency 02:08
action? 02:08
A. A final agency action? No. 02:08
Q. It even says that right on the 483s 02:08
itself, that it's not a final agency action; 02:08
correct? 02:08
A. I'd have to go back and look if I may. 02:08
Q. You don't want to trust me on that? 02:08
A. No. 02:08
Q. Find a 483. 02:08
A. Okay. 02:08
Q. You must have several in your stack. 02:08
THE VIDEOGRAPHER: Would you like me to 02:08

go off the record? 02:08

THE WITNESS: I got one right here. 02:08

BY MR. MORIARTY: 02:08

Q. You've given me out of your stack 02:08

Exhibit -- Plaintiffs' Exhibit 26, which is a 483 02:08

from March through May of 2008; correct? 02:08

A. Yes. 02:08

Q. And in the very top it says they are 02:08

inspectional observations and do not represent a 02:09

final agency determination regarding your 02:09

compliance. Does it say that right in the top box 02:09

of the document? 02:09

A. Yes. Put it on your stack. 02:09

MR. MORIARTY: Okay. How much time on 02:09

the tape? 02:09

THE VIDEOGRAPHER: 13 minutes. 02:09

MR. MORIARTY: Okay. 02:09

BY MR. MORIARTY: 02:09

Q. Let's talk about just background stuff 02:09

for a bit. Have you ever been sued? 02:09

A. Yes. 02:09

Q. What was the suit about? 02:09

A. Landlord-tenant. 02:09

Q. Any other suits? 02:09

A. Yes. 02:10

Q. What? 02:10
A. Probate. 02:10
Q. You were sued? A probate case? 02:10
A. Yes. 02:10
Q. Okay. Anything else? 02:10
A. No. 02:10
Q. What was the probate -- when in -- the 02:10
landlord-tenant case, were you the landlord? 02:10
A. I was. 02:10
Q. And in the probate case, just give me 02:10
the briefest description of what that was about. 02:10
A. I was made administrator of my father's 02:10
estate who died without a will. 02:10
Q. Got it. Okay. 02:10
So you have not been a Defendant in any other 02:10
cases. Have you ever been a Plaintiff in any 02:10
lawsuits? 02:10
A. No. 02:10
Q. Your report has appendices that list the 02:10
things that you reviewed; correct? 02:10
A. Correct. 02:10
Q. Then in addition to that, you brought 02:10
with you today Exhibits 107 and 108 which are 02:10
lists of things you reviewed online but did not 02:11
printout; correct? 02:11

A. Correct. 02:11
Q. Other than what is listed in your report 02:11
and 107 and 108, and the 484s and the Celsis 02:11
documents that we reviewed today and you told me 02:11
you just got, is there anything else you reviewed? 02:11
A. There may be some additional documents 02:11
in these folders over here. 02:11
Q. Are they in one discrete place so you 02:11
know what those additional documents are? 02:11
A. No. 02:11
Q. Did you review any deposition testimony 02:11
of any Actavis company witnesses? 02:11
A. Yes. 02:11
Q. Do you know which ones? 02:11
A. Hum. 02:11
Q. Are they listed somewhere? 02:11
A. They are listed. 02:12
Q. Are they listed in the report or in the 02:12
107, 108? 02:12
A. Probably both. 02:12
Q. Okay. Have you read the deposition 02:12
testimony of Dr. Semigran who is a cardiologist in 02:12
Boston I questioned him. 02:12
A. I don't recall. 02:12
Q. Did you read the deposition of a Ph.D. 02:12

by the name of Nelson. He's in Cincinnati. I questioned him. 02:12

A. I don't recall. I don't think so. 02:12

Q. All right. 02:12

A. Those two names don't ring a bell. I can check. 02:12

Q. Have you consulted with any other pharmaceutical experts in your work on this case -- subcontractors, in other words? 02:12

A. Expert witness? 02:13

Q. Yeah. 02:13

A. No. 02:13

Q. This is Exhibit 93. This is the resume of yours that we were supplied by the Plaintiffs' lawyers. Is it current and up-to-date? 02:13

A. I have a current copy that I can compare it against. Would you like me to do that? 02:13

Q. As quickly as you can. 02:13

A. Okay. Excuse me. I'll just scan through it, save time. 02:13

THE VIDEOGRAPHER: While we are doing that, we can change the tape. 02:14

The time is 2:17 p.m. We're going off the record. 02:14

(Short break) 02:18

THE VIDEOGRAPHER: The time is now 2:22 p.m. We are back on the record. This is the beginning of tape five. 02:18 02:18 02:19 02:19

BY MR. MORIARTY: 02:19

Q. Okay. So the question was does it look like your CV is up-to-date? 02:19 02:19

A. There are few things here that are different. 02:19 02:19

Q. Such as? 02:19

A. Such as if I recall right here, there's a couple of committees that I -- there's a committee that I don't sit on anymore. 02:19 02:19 02:19

Q. Okay. 02:19

A. And -- 02:19

Q. Is there anything significant that you do or have done or have published that is not on there? 02:19 02:19 02:19

A. Yeah, I've actually been hired as an adjunct Professor at St. Leo to do online education. 02:19 02:19 02:19

Q. Not a classroom? 02:19

A. No. Distance learning. 02:19

Q. What's the topic? 02:20

A. It's general science. 02:20

Q. Okay. Does Delphi have offices in North 02:20

Carolina? 02:20
A. No. 02:20
Q. Do you just spend the summers up there? 02:20
Was that why we were planning on doing this in 02:20
North Carolina in June? 02:20
A. Yeah, I'm engaged in a large consulting 02:20
project right now. 02:20
Q. Got it. How many employees does Delphi 02:20
have? 02:20
A. Two. 02:20
Q. Who are they? 02:20
A. Myself and my wife. Permanent. 02:20
Q. What's your wife's undergraduate degree 02:20
in? I promise I won't show her the tape. 02:20
A. Something like modern foreign languages. 02:20
Q. Okay. Does she have a graduate degree 02:20
in anything? 02:21
A. No. 02:21
Q. Have you ever consulted with Actavis, 02:21
Mylan, UDL, or Amide? 02:21
A. Consulted? 02:21
Q. Yes, consulted. 02:21
A. No. 02:21
Q. The Delphi web page indicates that your 02:21
business is woman-owned. I assume that's your 02:21

wife? 02:21

A. It is. 02:21

Q. And what is her job with the company? 02:21

A. On a functional basis -- I would have to go back and look at the sub-S form filing in order to see what her real title is in that paperwork, but the functional, she is the bookkeeper. 02:21

Q. And did she have independent resources, if you will, that she contributed to start and run the business? 02:21

A. Could you explain that a little more? 02:22

Q. Sure. I mean she owns at least 51 percent of the business; correct? 02:22

A. That's correct. 02:22

Q. And what was the contribution that led her to that ownership? Was it cash, was it a car, was it office equipment, what was it? 02:22

A. She and I formed the corporation together and we made it 51 percent her in order to take advantage of small business loans if they became available. 02:22

Q. All right. Now you list your clients or some of them at page 5 to 6 of this exhibit. 02:22

A. Uh-huh. 02:22

Q. Did any of those consultations have to 02:22

do with extra-thick tablets? 02:22
A. Because of confidentiality agreements, I 02:22
am not at liberty the discuss anything about 02:22
clients. 02:22
Q. I didn't ask which client and which 02:22
product. So I need to know whether any of those 02:22
had to do with extra-thick tablets. 02:22
A. No. 02:22
Q. Did any of them have to do with 02:22
normal-sized tablets with too much active 02:22
pharmaceutical ingredient? 02:23
A. From a consultant standpoint? 02:23
Q. Yes, sir. 02:23
A. Perhaps. 02:23
Q. In March of 2009, Watson had a recall 02:23
for a drug called Propafenone HCL that had too 02:23
much active pharmaceutical ingredient in it. Did 02:24
you consult with them on that project? 02:24
A. No. 02:24
Q. Now, what did Laboratory Management 02:24
Systems, Inc. do? What did they make? 02:24
A. They were a services company that 02:24
provided maintenance calibration -- IQ, OQ, PQ 02:24
services to the pharmaceutical industry in 02:24
addition to compliance concerns. 02:24

Q. So you did not -- whatever role you had there did not involve the manufacture of any pharmaceutical dose form; correct? 02:24

A. I consulted in the field. 02:24

Q. I'm asking whether LMSI didn't manufacture pharmaceutical -- 02:25

A. No, they did not manufacture, no. 02:25

Q. What did Restek Corporation do when you worked for them? 02:25

A. Restek's core business is GC and HPLC column technology. I designed, built, staffed, qualified after writing a business plan, the contract analytical laboratory for them. 02:25

Q. They did not manufacture any dose form of pharmaceutical products; is that correct? 02:25

A. That's correct. 02:25

Q. What did Somerset Pharmaceuticals do when you worked with them in '95 and '97? 02:25

A. We were a small pharmaceutical company that was doing research and development and supporting, when necessary, manufacturing of certain products. 02:26

Q. Did Somerset actually manufacture for sale and distribution solid oral dose pharmaceutical products? 02:26

A. Yes. 02:26
Q. What products? 02:26
A. Primarily Eldepryl, Selegiline hydrochloride, Parkinson, Alzheimer's. And we did a lot of R&D with respect to those forms. 02:26
Q. So what was your role specifically regarding the manufacture, the assembling of raw material, its blending, its tableting, its in-process testing, what was your role? 02:26
A. Our role was -- 02:26
Q. No. Your role. 02:26
A. My role? I was supervising the analytical laboratory, R&D laboratory, and quality control laboratory. 02:26
Q. So you would have supervised the QC lab that did finished product testing on that drug? 02:27
A. In support of application developments like ANDA. The QC lab that did release testing was not at that facility. 02:27
Q. All right. And not under your supervision. 02:27
A. Not for release testing, no. 02:27
Q. What did you do for UDL? 02:27
A. I was -- 02:27
Q. In 1994 and the first month of 1995. 02:27

A. I was an analytical research chemist. 02:27
Q. So did you do finished product testing 02:27
on solid oral dose pharmaceutical products? 02:27
A. Yes. 02:28
Q. What products? 02:28
A. It's been such a long time, I can't 02:28
recall specifics without guessing. 02:28
Q. Well, did you do any testing on 02:28
Digitek? 02:28
A. No. 02:28
Q. Did you have anything to do with the 02:28
design or formulation of blister packs? 02:28
A. No. 02:28
Q. Who was your supervisor with UDL? 02:28
A. My last supervisor was Anita Runyon. 02:28
Q. Do you know if she's still with UDL? 02:28
A. UDL, no. 02:28
Q. Does UDL still have facilities in Largo, 02:28
Florida, to your knowledge? 02:28
A. To my knowledge, no. 02:28
Q. Do you have any special training in or 02:29
expertise in pharmacovigilance? 02:29
A. No. 02:29
Q. Have you worked in pharmacovigilance for 02:29
a pharmaceutical company? 02:29

A. No. 02:29
Q. When you are called upon to consult in 02:29
the pharmaceutical industry, do you consult on 02:29
pharmacovigilance issues? 02:29
A. No. 02:29
Q. Do you ever -- do you have any special 02:29
training or expertise in FDA regulatory affairs? 02:29
A. No. 02:29
Q. Have you ever worked directly in the 02:29
quality assurance of the manufacturing side of the 02:29
production of a solid oral dose pharmaceutical 02:29
product? 02:29
A. As a permanent employee? 02:29
Q. Yes. 02:30
A. No. 02:30
Q. Have you been consulted on the QA 02:30
manufacturing side of solid oral dose 02:30
pharmaceutical production? 02:30
A. I have been involved in those 02:30
discussions with QA personnel, yes. 02:30
Q. And is this in your consulting role? 02:30
A. It is. 02:30
Q. How many times do you think you've done 02:30
that particular role over the years? 02:30
A. Interacting with QA? 02:30

Q. Directly involved with QA on the manufacturing side as opposed to the QC on the analytical chem side. 02:30

A. From a consulting standpoint? 02:30

Q. Yes. 02:30

A. The real number I couldn't give you an exact number, but most consulting tasks that I've done, you end up interacting with QA almost on a daily basis. 02:30 02:31

Q. Okay. When you've done your consulting, and when you were an employee in pharmaceutical businesses, was most of your GMP work regarding lab and lab equipment issues as opposed to manufacturing side issues? 02:31

A. A lot of my specialty is in the laboratory. In most cases the laboratory is -- ends up involved in manufacturing-related issues. They are usually discovered or potentially discovered in the laboratory first in my experience. 02:31

Q. Okay. I think my question was whether the bulk of your work either as a consultant or -- in the pharmaceutical business was on the lab side of GMPs as opposed to the manufacturing side, not whether there is some spillover. Is the bulk the 02:31 02:32

lab side? 02:32

A. There's a lot of overlap, but, yes, the bulk is in the lab. 02:32

Q. Have you ever had any publications about extra-thick tablets? 02:32

A. No. 02:32

Q. Have you had any publications about tablets of normal size but varying active pharmaceutical ingredient? 02:32

A. Could you say that again, please. 02:32

Q. Have you had any publications -- 02:32

A. Yes. 02:32

Q. -- about tablets of normal size but varying active pharmaceutical ingredient? 02:32

A. I have a publication with respect to TLC analysis of -- if I recall correctly; it's been a long time -- API and tablets, that look at different ingredients in there. 02:32

Q. But that's the lab analysis of tablets; correct? 02:33

A. That's correct, yes. 02:33

Q. Not about the root cause of the problem to begin with? 02:33

A. Actually, there's -- it does expand into that. 02:33

Q. Okay. 02:33
A. As I said, invariably things start out 02:33
in the lab and end up spilling over into the 02:33
manufacturing quality system. 02:33
Q. Are you a member of any organizations, 02:33
professional organizations? 02:33
A. I am. 02:33
Q. And which ones? 02:33
A. I have them listed here. Curiously 02:33
enough, I don't. 02:33
Q. So? 02:33
A. I -- 02:33
Q. What are you a member of? 02:33
A. I am a member of -- if my memory is not 02:33
complete, I apologize, but I have been a member of 02:33
the ACS. 02:34
Q. No, now. 02:34
A. Now I'm a member of the ACS. I have 02:34
been a member for a long time. 02:34
Q. The American Chemical Society? 02:34
A. It is. American Association of 02:34
Pharmaceutical Scientists, also American Society 02:34
of Quality. 02:34
Q. Do you know whether any of those 02:34
organizations have ethical guidelines regarding 02:34

testimony in court cases? 02:34
A. I don't know. 02:34
Q. Does your website have a section about your core competencies? 02:34
A. I'd have to go back and pull up the page. It's been a while. 02:34
Q. I wrote that in quotes so I may have quoted it directly. 02:34
A. Okay. 02:34
Q. If that -- 02:34
A. One doesn't normally visit your own website. 02:34
Q. One should. 02:34
A. Yeah. 02:34
Q. If one -- if there is a section on core competencies, does it say anything about manufacturing in there? 02:34
A. I don't recall. 02:35
Q. All right. Now, you have written a book apparently about validating chromatographic methods; is that right? 02:35
A. That's correct. 02:35
Q. Is that book still available? 02:35
A. It is. 02:35
Q. It was published in '06; is that right? 02:35

A. If that's what it says here on the resume, that would be the year. 02:35

Q. Have they asked you to do a second edition? 02:35

A. Not yet. 02:35

Q. Is it universally accepted that methods used in forensic work have to undergo validation? 02:35

A. Forensic work? 02:35

Q. Yeah. 02:35

A. I'm a not familiar with forensic analysis. 02:35

Q. Is it universally accepted in the pharmaceutical business that the test methods for things like finished product testing have to go through validation? 02:35

A. Absolutely. 02:35

Q. Have you ever done assay or content uniformity testing on Digoxin? 02:36

A. No. 02:36

Q. Have you ever developed an assay or content uniformity method for testing any solid oral dose pharmaceutical product? 02:36

A. Say that again. I'm sorry. I lost you. I was still thinking about the last question. 02:36

Q. Have you ever developed and validated a method to test for the potency of any solid oral dose pharmaceutical product? 02:36

A. I have been involved in that. 02:36

Q. How many times? 02:36

A. Solid oral doses? 02:36

Q. Yeah. 02:36

A. About three or four I would say. 02:36

Q. If you assume that you were going to develop a method to test the potency of a tablet, and you had never done that before -- 02:37

A. Uh-huh. 02:37

Q. -- okay, how long do you think it would take you to develop and validate the method? 02:37

A. From scratch? 02:37

Q. From scratch. 02:37

A. A new chemical entity? 02:37

Q. No, a common chemical entity but you've never done it before. 02:37

A. It really depends on the chemistry of the molecule. 02:37

Q. Give me the short side. 02:37

A. Short side? 02:38

Q. Yeah. 02:38

A. Develop a method? 02:38

Q. Yeah. 02:38
A. And validate it? 02:38
Q. Yeah. 02:38
A. This is when I go back and look at my 02:38
book. Approximately, from scratch? 02:38
Q. Yes, sir. 02:38
A. Approximately six to nine months from 02:38
scratch. 02:38
Q. So if somebody came to you and said this 02:38
is a test that from the time of starting the 02:38
validation, running the standards, the blanks, and 02:38
the sample that you were going to test, total of 02:38
two hours, that would be inconsistent with your 02:38
experience? 02:38
A. Validation? 02:38
Q. Yes, sir. 02:38
A. That's not a validation. 02:38
Q. Okay. When you talked earlier, you were 02:38
referring to something about chromatography. Is 02:38
the -- is the -- what does it mean if the results 02:39
of the test exceed the range of your standard? 02:39
What does it do to the validity of your test? 02:39
A. Please bear with me on this. 02:39
Q. Yeah. 02:39
A. I'm not sure I understand what you're 02:39

asking. 02:39

Q. Well, I'm not an analytical chemist so 02:39

I'm doing the best I can from memory. When you 02:39

run the standard, you get a range, don't you? 02:39

A. A range? 02:39

Q. Yeah, a range for what the results ought 02:39

to be on the standards? 02:39

A. Now, in the pharmaceutical industry with 02:39

respect to assay, you don't do a set of 02:39

standards. You do one standard. 02:39

Q. Okay. 02:39

A. And you come up with an acceptance 02:39

criteria up-front, through establishing 02:39

suitability of the methodology and the equipment 02:39

and then you confirm in most cases whether the 02:39

standards that you have in there are suitable for 02:40

intended use as the run is established. 02:40

Q. And aren't your results supposed to be 02:40

within the range of your standards? 02:40

A. Yeah, I am using term range -- 02:40

Q. Results of the actual test. 02:40

A. The standard is used to determine the 02:40

amount in the sample that you're analyzing, if 02:40

that's what you mean. 02:40

Q. Then if you test the sample and it 02:40

exceeds the range of your standard, what does it do with the validity? 02:40

A. It exceeds the amount? 02:40

Q. Yeah. 02:40

A. Then the -- the result initially is suspect. 02:40

Q. Okay. 02:40

A. And then it requires an investigation. 02:40

Q. All right. 02:40

THE WITNESS: Can we take a break, please? 02:40

MR. MORIARTY: Sure. 02:40

THE VIDEOGRAPHER: The time is 2:43 p.m. We're going off the record briefly. 02:40

(Short break) 02:46

THE VIDEOGRAPHER: The time is now 2:50 p.m. We are back on the record. 02:46

BY MR. MORIARTY: 02:47

Q. Earlier we were talking about process validation and you mentioned something about bulk stability hold time studies; okay? 02:47

A. Uh-huh. 02:47

Q. Now, I don't have the 438 regarding that but I have the Exhibit 171, November 9th, 2007, EIR from FDA; okay? 02:48

A. Okay. 02:48
MR. FITZPATRICK: I'm sorry. What was 02:48
the date? 02:48
MR. MORIARTY: The letter I have is 02:48
September -- November 9th. November 9th, 02:48
2007; okay? And it says: 02:48
"We are enclosing a copy of the 02:48
establishment inspection report for the 02:48
inspection conducted at your premises at 02:48
location on September 5th, 2007, et al.," and 02:48
then in here it addresses some earlier 483s; 02:48
okay? 02:48
THE WITNESS: Okay. 02:48
BY MR. MORIARTY: 02:48
Q. I want you to look at observation number 02:48
7 -- 02:49
A. Okay. 02:49
Q. -- in this EIR. 02:49
A. Okay. 02:49
Q. Does that -- does observation seven 02:49
correlate with what you were talking about before 02:49
about this bulk stability hold time issue? 02:49
A. To save time, do you recall what my A 02:49
number was that went with it when I looked at 02:49
this? 02:49

MR. ANDERTON: Yeah, A25. 02:49
THE WITNESS: 25? 02:50
MR. ANDERTON: Yes, page 41 of your report. 02:50
THE WITNESS: Great. Thank you. 02:50
MR. ANDERTON: Actually, the comment is on page 42. 02:50
THE WITNESS: Got you. Thank you. 02:50
I believe my information came directly from the warning label. 02:50
BY MR. MORIARTY: 02:50
Q. I'm asking you if this EIR discussion observation seven correlates to that warning letter. 02:50
A. I don't think so. I think that that was another observation from the previous inspection that was in 17 November, 2006, from what it looks. 02:51
If we go to my reference where I talk about -- hold on a second -- let's see. Oh, one page down. Excuse me. I misspoke. I was one line off in my own paper. Warning letter was issued 10 July for the August 2006 inspection of Little Falls. So my reference here is with respect to a warning letter for an inspection that was 10 July 02:51

to 10 August 2006. And this is 5 September to 28 September, 2007. So those are two different things. 02:52

So this is an additional observation with respect to problems potentially with bulk hold times. 02:52

Q. Go back to page 25 of 40 in Exhibit 171. It bears Bates page 505285. 02:52

A. Okay. All right. Page 25 of 40. 02:52

Q. Go to the top. It says "voluntary corrections." Do you see that? 02:52

A. I do see that. 02:52

Q. "Corrections to the previous FDA 483 were reviewed with Wanda Eng, director of corporate compliance for Actavis U.S. The previous 483 observations and the associated corrections, included below." 02:52

A. Okay. 02:52

Q. Do you see that? 02:52

A. I do see that. 02:52

Q. All right. So this observation seven is at least referring to the bulk stability data; correct? 02:52

A. I'm not sure. I'm not trying to be difficult here. I'm just not sure. 02:53

Q. Page 31 of 40, observation seven says the stability data recorded as that of bulk stability hold time studies are actually obtained from the testing of the following packaged finished products. 02:53

Do you see that? 02:53

A. I do. 02:53

Q. Okay. 02:53

A. I'm just trying to make sure we're talking about the same one, or is this an additional observation from the -- this current inspection? 02:53

Q. Well, let's talk about this one. 02:53

A. Okay. "This one" being this observation right here? 02:53

Q. Right here. Observation seven. 02:53

A. Okay, okay. 02:53

Q. Digitek isn't mentioned, is it? 02:53

A. The corrections here would indicate that "All of the bulk hold time studies have been repeated on each of the above-listed products at time points beyond three months as immediate corrective action." 02:53 02:54 02:54 02:54

So based on that statement, it appears that that bulk hold time stability study -- for 02:54

whatever reason it's blacked out, which we don't know what it is, and I'm not sure why it's blacked out. Do we know? 02:54

Q. Let's deal with one question at a time. 02:54

A. Okay. That -- 02:54

Q. It was remediated and resolved to the satisfaction of FDA, was it not? 02:54

A. For these three products. 02:55

Q. Yes; right. 02:55

A. For these three products, yes. 02:55

Q. And Digitek is not even mentioned in observation seven, is it? 02:55

A. Unless it was blacked out. 02:55

Q. Well, we don't black out Digitek in the Digitek litigation; okay? 02:55

A. Okay, okay. 02:55

Q. So Digitek isn't mentioned? 02:55

A. It is not, no. 02:55

Q. Do you subscribe to or regularly review any journals in the pharmaceutical industry? 02:55

A. And, again, I'm not trying to be difficult. How are you -- journals. What do you mean by a journal? 02:55

Q. Like any journal whether it's online or not. A scholarly collection of publications by -- 02:56

A. Peer-reviewed journal? 02:56
Q. Yes. 02:56
A. I will pull up articles that are pertinent but as far as reading a journal, no. 02:56
Q. Well, how do you know there are articles out there that are pertinent? 02:56
A. FDA notices from their websites and my trade magazines have references to articles, and I keep current by my trade publications that come out sometimes every two weeks that funnel you back to the things that are important. 02:56
Q. What trade publications do you get? 02:56
A. The AAPS magazine, CEN news. 02:56
Q. What is AAPS? 02:56
A. That's the American Association of Pharmaceutical Scientists. 02:56
Q. Okay. And are there any other ones you get? 02:56
A. Chemical and Engineering News, which is a publication of the American Chemical Society. 02:56
Q. Anything else? 02:56
A. American Society Quality periodically puts out notices with respect to compliance issues. They also have a magazine that comes out like once a month, too, that references that. And 02:56 02:57

I read books. 02:57

Q. Do you know what the FDA's application integrity policy is? 02:57

A. Never heard of it. 02:57

Q. In your experience, are FDA inspectors regularly on the lookout for falsified data in submissions like NDAs and ANDAs as well as routine reporting? 02:57

A. I think that's one of the things they are cognizant of. 02:57

Q. Are the -- if FDA detects document integrity problems, is their response typically swift and severe? 02:57

A. Swift no doubt. It depends on the document problem. Obviously there are different flavors of documentation problems. 02:58

Q. Do you have experience with this topic? 02:58

A. Yeah. 02:58

Q. Do you consider yourself an expert in it? 02:58

A. In FDA addressing documentation issues? 02:58

Q. Right. 02:58

A. Yes. 02:58

Q. I mean where they suspect that the documents are falsified, do you have experience in 02:58

that? 02:58
A. I have had direct experience of that in 02:58
the last eight months. 02:58
Q. All right. Now nowhere in your report 02:58
did I see you render any opinion that Actavis's 02:58
documents were falsified or had questionable 02:58
integrity. 02:58
Am I correct about that? 02:58
A. I don't believe there is any statement 02:59
to that effect in the report. 02:59
Q. And can you point me to any FDA 483 02:59
warning letter or other regulatory document that 02:59
cites Actavis for having suspicious or falsified 02:59
documentation? 02:59
A. If I'm not mistaken -- and we have to go 02:59
back and look -- but there should be several 02:59
notations with respect not documenting things as 02:59
they occur, which would be considered a 02:59
documentation issue. 02:59
Q. I'm talking about falsifying. 02:59
A. Falsifying? Falsifying, no. 02:59
Q. That's what I'm asking about. 02:59
A. Falsifying is very difficult to assess 02:59
unless you're at the facility as well, so... 02:59
Q. Well, FDA was at the facility on several 02:59

occasions in '06, '07 and '08, were they not? 02:59
A. Yes. 03:00
Q. Does an ANDA contain a -- let me 03:00
withdraw that. 03:00
How much are you charging for your time to 03:00
review materials in this consulting work? 03:00
A. As strange as it sounds, my bookkeeper 03:00
does the billing. I can't honestly answer that 03:00
question what the billing rate is. We negotiated 03:00
a rate, it's in an e-mail, there was some 03:00
additional discussions, but I don't know what's 03:00
going on in the invoice to be honest with you. 03:00
Q. What's the rate? 03:00
A. Again, as strange as it sounds, I have 03:00
to go back and look at the specific e-mail. 03:01
Q. You don't want me hauling your wife down 03:01
here to talk about this. 03:01
A. Oh, no, no. 03:01
Q. Do you know what the total amount billed 03:01
and received for your company to date is on this 03:01
consulting arrangement? 03:01
A. Not off the top of my head, no. 03:01
Q. Is it over $20,000? 03:01
A. I would say that's a fair assessment. 03:01
Q. Is it over $35,000? 03:01

A. I'd say that's a fair assessment. 03:01
Q. I would like you to find out what your 03:01
rate is and what the billings and receipts are to 03:01
date; okay? 03:01
A. Okay. 03:01
Q. Because we're not going to finish 03:01
today. So somebody gets to come back and question 03:01
you on another day about those things; okay? 03:01
A. Okay. 03:01
Q. Now, when a company is on consent 03:01
decree, isn't it required that they comply with 03:01
GMPs? 03:02
A. If a company gets placed under a consent 03:02
decree, if it's with respect -- because there are 03:02
several different types of consent decrees that go 03:02
outside the GMPs -- the company goes into the 03:02
voluntary agreement of consent decree if they've 03:02
had chronic and sustained problems with respect to 03:02
compliance with the GMPs, in my experience. 03:02
Q. Are you done with your answer? 03:02
A. Yes, sir. 03:02
MR. MORIARTY: That wasn't my question. 03:02
THE WITNESS: I'm sorry. 03:02
BY MR. MORIARTY: 03:02
Q. My question was when you're on consent 03:02

decree, aren't you required to comply with GMPs? 03:02
A. You are required to comply with GMPs 03:02
whether you are on consent decree or not. 03:02
Q. Well, what does the FDA do when you are 03:02
on consent and you are found not to be in 03:02
compliance with GMPs? 03:02
A. Even if you are under consent decree, 03:02
the agency continues to audit and make findings 03:03
and they continue on outside of that agreement, 03:03
just like they would normally. 03:03
Q. All right. So you know that when Amide 03:03
came off consent decree in 2000, 2002, somewhere 03:03
in there, it was because of sustained compliance 03:03
with GMPs; correct? 03:03
A. They had demonstrated they had fulfilled 03:03
the obligations of the consent decree. 03:03
Q. I would like you to look at Exhibit 22, 03:04
please. Do you know whether you have seen this 03:04
letter before? It's a warning letter dated 03:04
January 9th, 2007. 03:04
A. Okay. 03:05
Q. Do you know whether you've seen it 03:05
before? 03:05
A. Not without looking at my list, no. 03:05
Q. Okay. 03:05

A. Some warning letters weren't available. 03:05
Q. I want you to go to the second to last 03:05
page of this document. The Bates numbers are a 03:05
little bit cut off, but it's 2883 something. 03:05
A. Something, got you. 03:05
Q. Do you see that? 03:05
A. I do, sir. 03:05
Q. In the last paragraph -- 03:05
A. Uh-huh. 03:05
Q. -- the FDA said: 03:05
"We feel that to provide such assurance, your 03:05
firm should promptly initiate an audit program by 03:05
a third-party having appropriate cGMP expertise to 03:05
provide assurance that all marketed lots of drug 03:06
products that remain within expiration have their 03:06
appropriate identity, strength, quality and 03:06
purity." 03:06
Do you see that? 03:06
A. Where is that? I missed it. 03:06
MR. KERENSKY: It's last sentence of the 03:06
paragraph. 03:06
THE WITNESS: The last sentence of the? 03:06
MR. KERENSKY: Last paragraph. 03:06
THE WITNESS: Last paragraph; okay. I'm 03:06
sorry. "We feel that to provide such 03:06

assurance, your firm should promptly initiate" -- yes, I see that. 03:06

BY MR. MORIARTY: 03:06

Q. Okay. 03:06

A. Yes. 03:06

Q. Do you know what Actavis did in response to Exhibit 22? 03:06

A. Specifically, no. However, I know that consulting firms were involved at some point. 03:06

Q. Do you know what consulting firms? 03:07

A. With respect to this specific warning letter? 03:07

Q. Yeah. 03:07

A. I can't tell you that. 03:07

Q. Do you know anything about Quantic Regulatory Services? 03:07

A. I do. 03:07

Q. What do you know about them? 03:07

A. I have worked as subcontractor for them. 03:07

Q. Are they considered to be a reliable firm in the pharmaceutical field? 03:07

A. They are to me, yes. 03:07

Q. Well, FDA is specifically saying your firm should initiate an audit program by a third-party having appropriate cGMP expertise. Is 03:07

Quantic Regulatory Services considered to have appropriate cGMP expertise? 03:07

A. Yes. 03:07

Q. Okay. Have you ever seen Exhibit 23? 03:07

A. Yes. 03:08

Q. All right. Exhibit 23 is a letter dated December 24th, 2007, to FDA from Actavis; correct? 03:08

A. Yes. 03:08

Q. Enclosing reports from Quantic; is that right? 03:08

A. Right, that appears to be. 03:09

Q. Okay. Now, I assume you didn't work for Quantic on this project, did you? 03:09

A. No, sir. 03:09

Q. So if we go to -- do you know how many Digitek batches Quantic looked at? Batch records I should say. 03:09

A. No. 03:09

Q. Now, Quantic specifically found in its batch review at page 1867209. 03:09

A. I have that page. 03:10

Q. All right. If you look sort of right in the middle of the page they say: 03:10

"Based upon this review, it is QRS's opinion that except as set forth below, the batch records 03:10

reviewed did not contain non-conformances or deficiencies that are likely to have had a material, adverse impact on the identity, strength, quality or purity of such other batches." 03:10 03:10 03:11 03:11 03:11

Okay? 03:11

Now do you have any data available to you on which you could conclude that you disagree with QRS about the batch records that they reviewed? 03:11 03:11 03:11

A. The batch records they reviewed? 03:11

Q. Correct. 03:11

A. No. 03:11

Q. Do you know how many of the Digitek batches that they reviewed -- the Digitek batch records that they reviewed were recalled Digitek batches? 03:11 03:11 03:11 03:11

A. I'm sorry. Say that again. 03:11

Q. Do you know how many of them were recalled Digitek batches? 03:11 03:11

A. No. 03:11

Q. If just assuming that QRS's conclusion was correct that they have reliably confirmed the identity, strength, quality, and purity of the batch records that reviewed; okay? 03:11 03:12 03:12 03:12

A. That they reviewed. 03:12

Q. That they reviewed, that would mean that those batches were not even adulterated; is that correct? 03:12

A. What they reviewed was, correct. That's what you can say. The batch record. And apparently here laboratory testing represents part of that, which may or may not show the product's adulterated. 03:12

Q. So one way that the FDA -- well, do you have any evidence that the FDA accepted or rejected this remediation of that part of the January 2007 warning letter? 03:12

A. Yesterday was the first time I saw this, so I have nothing other than this. 03:13

Q. All right. Well, would it be correct -- I would I be correct in assuming that batch records -- batch record reviews when conducted as QRS did would be one way to determine if batches are adulterated? 03:13

A. It's -- it is a measure to take and to go back to try to determine, potentially. 03:13

Q. Okay. Is there some reason why you didn't review batch records? Let's assume you reviewed one or two. 03:13

A. Reviewed the ones in the ANDA. 03:13

Q. Because you don't remember. Is there some reason why you didn't review batch records from '06, '07, and '08? 03:13

A. I reviewed the documentation that I was requested to review and provided to me in addition to the ones I was asking for. That's it. 03:13

Q. I understand that. 03:14

A. Yeah. 03:14

Q. But you had access to an online repository. Yet all these documents -- 03:14

A. I did not have access to all the documents. They were selectively provided me in a folder. 03:14

Q. Did you ask to review batch records? 03:14

A. I provided a list of things that I asked. I'd have to look at that to determine whether I asked for batch records. 03:14

Q. Do you have that list here? Because we asked in the notice of deposition -- well, we'll get into that at some point. 03:14

A. Right. 03:14

Q. That you bring all your correspondence? 03:14

A. Yes, I got -- I have it on a hard drive. All my e-mail communications is on a hard drive. 03:14

Q. So you believe that in an e-mail you corresponded to some Plaintiffs' lawyers, Fred, Meghan, whoever it happened to be -- 03:14

A. Uh-huh. 03:15

Q. -- that you that you wanted to see documents. 03:15

A. Yes. 03:15

Q. And do you remember now whether they supplied all the documents you asked for? 03:15

A. I'm not sure. I'd have to look at the list to see what was provided. 03:15

Q. Do you remember now whether batch records was some of things that you asked for? 03:15

A. I can't tell you with certainty, no, I can't. 03:15

Q. And do you have that hard drive with you? 03:15

A. I do. 03:15

Q. But it's on your laptop or did you -- 03:15

A. It's external. 03:15

Q. Put it on a thumb drive? 03:15

A. It's an external drive. 03:15

Q. Is it like a little thumb drive? 03:15

A. A Passport hard drive. 03:15

Q. Is that a copy of the hard drive or is 03:15

that the hard drive? 03:15

A. That is the hard drive. When I first 03:15

started doing the work, since I've never done it 03:15

before, their recommendation was that everything 03:15

with respect to this go on that hard drive. 03:15

Q. Okay. Certainly -- I mean we're going 03:16

to need at some point access to that hard drive; 03:16

okay? 03:16

A. Sure. 03:16

Q. So don't delete anything. 03:16

A. Oh, no, no. 03:16

Q. We'll just have to figure out 03:16

logistically how we can do that. 03:16

A. Okay. 03:16

Q. How many times have you worked with 03:16

Quantic Regulatory Services? 03:16

A. As far as consulting jobs go? 03:16

Q. Yes, sir. 03:16

A. Let's see. I have worked on the Wyeth 03:16

consent decree, the Schering Plough consent 03:16

decree, and I believe one other. To the best of 03:16

my knowledge three. 03:16

Q. Have you worked with QRS in some other 03:17

capacity besides consulting? 03:17

A. No. 03:17